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| 513 7590 09/26/2008 WENDEROTH, LIND & PONACK, L.L.P. 2033 K STREET N. W. SUITE 800 WASHINGTON, DC 20006-1021 | | | | |
| EXAMINER | | | | |
| TSAY, MARSHA M | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary**Application No.**

10/532,678

Applicant(s)

ISHIKAWA ET AL.

Examiner

Marsha M. Tsay

Art Unit

1656

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 June 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/ICE)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

This Office action is in response to Applicants' remarks received June 27, 2008.

Applicants' arguments have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous Office actions are hereby withdrawn.

Claims 1-8 are pending and currently under examination.

Priority: The request for priority to JAPAN 2002-328243, filed November 12, 2002, is acknowledged.

Objections and Rejections

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 6, 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saitoh et al. (US 6638562; previously cited) in view of Nagano et al. (JP 5043597; IDS 04.26.05). Claim 1 has been given its broadest and most reasonable interpretation, i.e. a process for producing soybean protein comprising heating a soybean protein solution under acidic conditions, and then fractionating it (ionic strength 0.02, pH 4.5-5.6) into a soluble fraction and an insoluble fraction. In Example 2, Saitoh et al. disclose a process for producing soybean protein comprising heating a solution of defatted-soybean milk at pH 5.9 to 40°C (col. 9 lines 10-14). Saitoh et al. further disclose that phytase was added to the soybean protein solution and fractionated to obtain an

insoluble fraction and a soluble fraction (col. 9 lines 16-20). Saitoh et al. disclose a 7S and an 11S globulin protein with a phytic content of 0.05% weight of protein (col. 9 line 18, lines 30-35). Saitoh et al. do not teach "fractionation conditions" at an ionic strength of 0.02 and pH of 4.5-5.6.

Nagano et al. disclose a method for fractioning 7S protein which comprises adjusting ionic strength and pH of a protein-containing solution into specific ranges to remove an insoluble fraction and further adjusting the ionic strength and pH to collect the formed insoluble fraction (JP 5043597 abstract; IDS 04.26.05). Nagano et al. disclose de-fatted soybeans were fractionated at an ionic strength of 0.2-0.3 and at a pH 4.8-5.2 to obtain an insoluble fraction (that is subsequently removed) and a soluble fraction (supernatant containing 7S protein). Further fractionation of the supernatant liquid allows a 7S protein of greater than 90% purity to be obtained.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Saitoh et al. by using the fractionation conditions (ionic strength 0.2, pH 4.8-5.2) of Nagano et al. during the fractionation process of Saitoh et al. in order to obtain a soluble fraction and an insoluble fraction (claims 1-4, 6, 8). The motivation to do so is given by Nagano et al., which disclose that a high purity 7S protein can be obtained from soybean protein by adjusting the ionic strength and pH value of the protein-containing solution to obtain a soluble fraction (7S protein) and an insoluble fraction.

In their remarks, Applicants assert that according to the present invention, an insoluble fraction (containing 11S globulin) can be separated, at a rapid separation-precipitate rate, by

heating a solution containing protein under acidic conditions, and then fractionating it at an ionic strength of 0.02 or more and pH of 4.5-5.6. Saitoh et al. do not teach or suggest that an insoluble fraction (which contains 11S globulin) can be separated by fractionating the solution containing soybean protein, which has been heated under acidic condition at an ionic strength of 0.02 or more and pH 4.5-5.6. Applicant's arguments have been fully considered but they are not persuasive.

As noted above, Saitoh et al. disclose a method of heating a soybean protein-solution under acidic conditions and then fractionating it to separate into a soluble fraction and an insoluble fraction (col. 9, example 2). It is noted that Saitoh et al. do not teach an ionic strength of 0.02 and a pH of 4.5-5.6 during the fractionating. However, this deficiency is believed to be remedied by the Nagano et al. reference, which teach fractionating a soybean protein-solution at an ionic strength of 0.02 and pH 4.5-5.6 to separate into a soluble fraction and an insoluble fraction can yield a high-purity 7S protein. Therefore, Saitoh et al. is still believed to be relevant art under 103(a) in view of Nagano et al.

Claims 5, 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saitoh et al. (US 6638562; previously cited) in view of Nagano et al. (JP 5043597; IDS 04.26.05). The teachings of Saitoh et al. are outlined above. Saitoh et al. teach a ratio of 7S globulin/(11S globulin + 7S globulin) is 0.9 in the soluble fraction (col. 9 lines 30-40). Claims 5-7 recite a content of a polar lipid extracted by a mixed solvent of chloroform and methanol is 1% by weight or 2% by weight or less, respectively, which can include 0%; therefore, the instant

process does not necessarily have to comprise the extraction step by a mixed chloroform and methanol solvent. Saitoh et al. do not teach a further fractionation step of the soluble fraction.

The teachings of Nagano et al. are outlined above and summarized herein. Nagano et al. disclose de-fatted soybeans were fractionated at an ionic strength of 0.2-0.3 and at a pH 4.8-5.2 to obtain an insoluble fraction (that is subsequently removed) and a soluble fraction (supernatant containing 7S protein). Nagano et al. disclose an additional fractionation step of the supernatant liquid (soluble fraction) at an ionic strength of 0.2 and a pH 4.6-5.0 allows a 7S protein of greater than 90% purity to be obtained.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Saitoh et al. by further fractionating the soluble fraction (containing 7S protein) as suggested by Nagano et al. in the process of Saitoh et al. (claim 5). Since Saitoh et al. disclose that the soluble fraction has a contamination rate of 2.9% of 11S protein (col. 9 line 39), one of ordinary skill would be motivated to add the additional fractionation step of Nagano et al. and expect to have reasonable success in obtaining a high purity 7S protein product since Nagano et al. suggest the soluble fraction (containing 7S protein) can be further fractionated to obtain a 7S protein having greater than 90% purity

Saitoh et al. teach a ratio of 11S globulin/(11S globulin + 7S globulin) of 11S globulin protein is 0.9 in the insoluble fraction (col. 9 lines 30-40). Saitoh et al. do not teach a further fractionation step of the insoluble fraction.

However, in view of Nagano et al., it would have been obvious to one of ordinary skill in the art at the time the invention was made to further fractionate 11S globulin protein from the insoluble fraction obtained by the fractionation process of Saitoh et al. (claim 7). The motivation

to do so is provided by Saitoh et al. which discloses that the insoluble fraction has a contamination of 7.0% of 7S globulin (col. 9 line 39); therefore, one of ordinary skill has a reasonable expectation of success in further fractionating the 11S globulin protein of Saitoh et al. because a further separation step will yield a purer 11S globulin protein product. In view of Nagano et al., it would be reasonable for one of ordinary skill to extend the same reasoning as noted for further fractionating the soluble fraction to further fractionating the insoluble fraction.

The reasons for maintaining the Saitoh et al. reference is the same as noted above. The deficiencies of Saitoh et al. are believed to be remedied by Nagano et al.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marsha M. Tsay whose telephone number is (571)272-2938. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Maryam Monshipouri/

Primary Examiner, Art Unit 1656

September 19, 2008